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16. ABSTRACT

The U. S. Environmental Protection Agency has implemented a rigorous quality assurance (QA) program to ensure that the performance data generated during their Superfund Innovative Technology Evaluation (SITE) Demonstration projects are of known and adequate quality to support decisions to use such technologies for hazardous waste site characterizations or remediations. A general overview of the ways in which this QA program has been conducted and of the results it has produced is presented.

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Quality Assurance for the SITE Program Demonstrations

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The U.S. Environmental Protection Agency has implemented a rigorous quality assurance (QA) program to ensure that the performance data generated during their Superfund Innovative Technology Evaluation (SITE) Demonstration projects are of known and adequate quality to support decisions to use such technologies for hazardous waste site characterizations or remediations. A general overview of the ways in which this QA program has been conducted and of the results it has produced is presented.

The Superfund Innovative Technology Evaluation (SITE) Program is one of the major approaches the U.S. Environmental Protection Agency has taken to examine the effectiveness of alternative waste treatment technologies to replace land-based disposal and containment, and to provide safe, permanent, cost-effective cleanup options for use at hazardous waste sites. Many of these new technologies may soon be included in the next generation remediation strategies for Superfund, Regional, state, and other hazardous waste sites. In order to avoid wasting millions of industry and taxpayer dollars on ineffective or improperly applied cleanup strategies, it is absolutely essential that the data generated during the SITE Demonstration projects be of known and adequate quality for strategic decision-making.

The EPA has long recognized the need for quality assurance (QA) to ensure that environmental sampling and analysis data are of known quality. Virtually every major project supported by the EPA now requires the development and approval of a detailed QA project plan prior to project start-up. The strategic importance and high public visibility of the alternative technology evaluations conducted under the SITE Program has led to the establishment of more rigorous QA planning requirements than are usual for similar, non-SITE projects. Additional QA activities, such as external audits and final report reviews, are also conducted to ensure that the specifications of the approved QA project plan are followed throughout the project.

A brief examination of the ongoing SITE Demonstration process and of the specific technologies selected for evaluation provides an interesting illustration of the variety of conditions for which specific QA procedures have been and are being implemented.

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SITE Demonstration Program

In mid-February 1986, nearly eight months before Congress passed the Superfund Amendments and Reauthorization Act of 1986 (SARA), the EPA began soliciting proposals for full- and pilot-scale demonstrations of innovative waste treatment technologies that could provide environmentally safe, economical, effective, and permanent solutions to hazardous waste disposal problems. With the enactment and subsequent funding of SARA, the EPA received the necessary authorization to conduct such technology demonstrations, and by December 1986, the Superfund Innovative Technology Evaluation (SITE) Program was formally established and became fully operational.[1]

SARA directs the EPA to promote the rapid development of alternative waste treatment technologies for the cleanup and disposal of hazardous wastes, and it defines alternative technologies as "those technologies, including proprietary or patented methods, which permanently alter the composition of hazardous waste through chemical, biological, or physical means so as to significantly reduce the toxicity, mobility, or volume (or any combination thereof) of the hazardous waste or contaminated materials being tested." Section 209(b) of SARA also authorizes the EPA to use hazardous wastes from actual Superfund sites to conduct alternative technology demonstrations, thereby enabling the collection of performance data that will be representative of the technologies' capabilities for general use in hazardous waste cleanup operations.

In order to accelerate the development of promising alternative technologies under the SITE Program, the Office of Research and Development (ORD) and the Office of Solid Waste and Emergency Response (OSWER) have developed the following categorical definitions:

- *Alternative Technology* (as per SARA). Any waste treatment and disposal technology, other than land disposal, that provides a permanent cleanup solution.
- *Available Technology*. An existing alternative technology whose safety, cost, and performance characteristics have already been proven in full-scale use.
- *Innovative Technology*. A fully-developed alternative technology for

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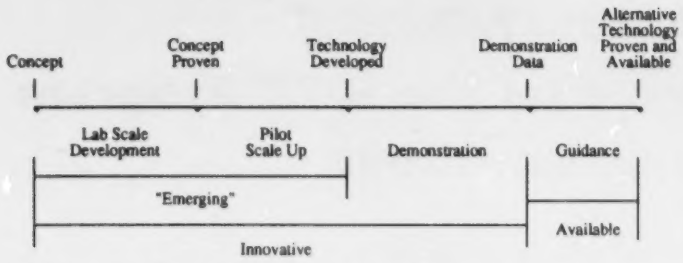

Figure 1. Development Process for alternative technologies.

which cost and/or performance data are incomplete or unavailable, thereby hindering its routine use at hazardous waste sites.

- *Emerging Technology*. An alternative technology that is not yet fully developed and requires further research and development at the laboratory- or pilot-scale levels.

Figure 1 illustrates the relationships among these alternative technology categories and indicates generic milestones through which a given technology must pass in the process of its development.

The SITE Program was designed to foster the development of alternative technologies at every level of development, but the primary focus of SITE has been the demonstration program for fully-developed, innovative technologies. Table I lists the innovative technologies selected from the 1986 and 1987 solicitations that currently are involved in the SITE demonstration process. At the time of this writing, the EPA is nearing completion of the selection process for innovative technologies proposed for demonstration in response to the third SITE solicitation, conducted in 1988, but demonstrations for the technologies selected thus far are only in the early stages of planning and are therefore not considered here.

The technologies listed in Table I span a fairly representative range of waste treatment alternatives from thermal destruction to immobilization to extraction to biological degradation. Most of the demonstrations have been scheduled to take place at Superfund sites, although a few have been or will be conducted on privately managed waste sites (e.g., the GE/Hialeah site); at one of the EPA's Test & Evaluation facilities (e.g., the Combustion Research Facility in Arkansas); or at the technology developer's site (e.g., the Westinghouse/Waltz Mill facility). The demonstration site selections are carefully made to match waste types to the technologies to be evaluated, so as to provide realistic tests of the developers' claims. For example, the Superfund site in Groveland, Massachusetts, was chosen for evaluation of the Terra Vac, Inc. in-situ vacuum extraction technology because the predominant pollutants at the site were volatile chlorinated hydrocarbon solvents and because the geographical characteristics of the site made remediation by excavation impractical. Similarly, the Douglassville disposal site in Pennsylvania was selected to demonstrate the Hazcon, Inc., solidification/stabilization technology, since the waste at the site consisted of oily sludges and con-

Table I. SITE program technologies.

Developer	Technology	Location of demonstration
First SITE Solicitation (SITE-001)		
American Combustion Technologies, Inc.	Pyretron™ Oxygen Burner	EPA Combustion Research Facility Pine Bluff, AR (Region 6)
Haztech/Shirco	Infrared Thermal Destruction	Peak Oil Site; Brandon, FL (Region 4)
Shirco Infrared Systems, Inc.	Infrared Thermal Destruction	Rose Township/Demode Road Site Rose Township, MI (Region 5)
Hazcon, Inc.	Solidification/Stabilization	Douglassville Disposal Site Douglassville, PA (Region 3)
Westinghouse Electric Corporation	Pyroplasma System	Westinghouse Facility Waltz Mill, PA (Region 3)
Westinghouse Electric Corporation	Electric Pyrolyzer	Project Removed From Active Status
Terra Vac, Inc.	In-Situ Vacuum Extraction	Valley Manufacturing Site Groveland, MA (Region 1)
Ogden Environmental Services (formerly GA Technologies)	Circulating Bed Combustor	McColl & Stringfellow Waste at Ogden Facility (Region 9)
Resources Conservation Company	Solvent Extraction (BEST)	Not Identified
International Waste Technologies	In-Situ Solidification	GE Site; Hialeah, FL (Region 4)
Detox Industries, Inc.	Biological Process for Organics	Project Removed From Active Status
Second SITE Solicitation (SITE-002)		
Air Products and Chemicals, Inc.	Fluid Bed Biological Systems	Project Removal From Active Status
GeoSafe Corporation	In-Situ Vitrification	Not Identified
CF Systems Corporation	Solvent Extraction	New Bedford Harbor, MA (Region 1)
Chemfix Technologies, Inc.	Chemical Fixation/Stabilization	Portable Equipment Company Site Clackamas, OR (Region 10)
MoTec, Inc.	Liquid/Solid Contact Digestion	Not Identified
Retech, Inc.	Plasma Heat	Butte-Silverbow Site Butte, MT (Region 8)
Sanitech, Inc.	Ion Exchange	Not Identified
Separation and Recovery Systems, Inc.	Solidification/Stabilization	Not Identified
Soliditech, Inc.	Solidification	Imperial Oil Company, Inc. Site Morganville, NJ (Region 2)
Waste Chem Corporation	Solidification	Woodland Rte 532 Site Woodland Township, NJ (Region 2)
Zimpro Environmental Control Systems	Powdered Activated Carbon/Biological	Not Identified

taminated soils containing a variety of volatile organic solvents, PCB's, and lead, which could provide a rugged test of the developer's claims for immobilization of organic and inorganic pollutants.

The site selection process is frequently complex, since, in addition to the technical considerations of matching technology to waste type, most site selections require negotiations with the technology developer, the regional waste management authority, the site owner, and the surrounding community. These considerations, coupled with developers' technical difficulties in a few instances, have slowed the SITE Demonstration process for some of the innovative technologies involved in the program. The majority of the demonstrations, however, have proceeded at a pace appropriate to their multimillion dollar magnitude. At the time of this writing, six of the demonstration projects from the first SITE solicitation have been completed, and drafts of the final reports have been submitted for all of them. In addition, two demonstration projects from the second solicitation are currently being conducted, and laboratory analyses are already under way for one of these.

After a site or a waste has been chosen for demonstrating a particular cleanup technology, a detailed planning process begins. Each SITE project must include a fully-developed set of demonstration planning documents which (a) specify all of the necessary site requirements (e.g., set-up space, utilities, legal access, personnel support, proximity to support facilities, safety and security provisions); (b) set forth the detailed operating conditions for the treatment process, including all process parameters, system calibration requirements, operating logs, background data, etc.; (c) define the demonstration schedule (e.g., for set-up, operation, decontamination, takedown, etc.) and the project organization and responsibilities; (d) specify the detailed objectives and procedures for sampling and analysis; (e) establish the requirements and procedures for quality assurance and quality control; and (f) present the detailed health and safety requirements and procedures. Although the technology developer's input and cooperation are required for effective planning, his primary responsibility, as defined in the SITE Strategy and Program Plan[1] and in other SITE documents[2,3] is to provide and operate the technology. The primary responsibility for demonstration plan preparation, then, lies with the EPA.

Development of the detailed Demonstration Plans, Site Preparation Plans, Sampling & Analysis Plans, QA Project Plans, and Health & Safety Plans required for SITE projects is an enormous undertaking. In order to provide the needed resources, the EPA's Risk Reduction Engineering Laboratory (RREL), which officially conducts the SITE Demonstration Program, has used a system of contractors from private industry to provide support for planning and conducting the demonstration process. Prime contractors, which have included Enviresponse, Inc., Science Applications International Corporation, and PRC Environmental Management, Inc., have been employed to perform the overall planning, coordination, and management of the demonstration projects. Several sampling and analytical (S&A) contractors, including Acurex Corporation, Alliance Technologies, NUS Corporation, Radian Corporation, PEI Associates, and Science Applications International Corporation, together with their numerous subcontractors, have provided the necessary expertise to develop and execute the appropriate, detailed S&A Plans and QA Project Plans for the SITE demonstrations. The need for this variety of contractors and subcontractors becomes apparent when it is realized that, in addition to coordination of the needs and efforts of developers, regional authorities, site owners and managers, S&A contractors, and local communities, the typical SITE project can require the determination of over 100 separate chemical species and waste characteristics (e.g, volatile and semivolatile organic compounds, pesticides and PCB's, dioxins and furans, metals, cyanide, sulfide, HCl, total particulates, total organic carbon, oil & grease, pH, etc.) for its various sample types. Rarely can a single contractor provide both the capability and the capacity to perform all of the sampling and analytical tasks for a given SITE demonstration.

The EPA also relies on its contractor system for the preparation of draft demonstration reports. Following the completion of the active demonstration, sampling, and analysis phase, the

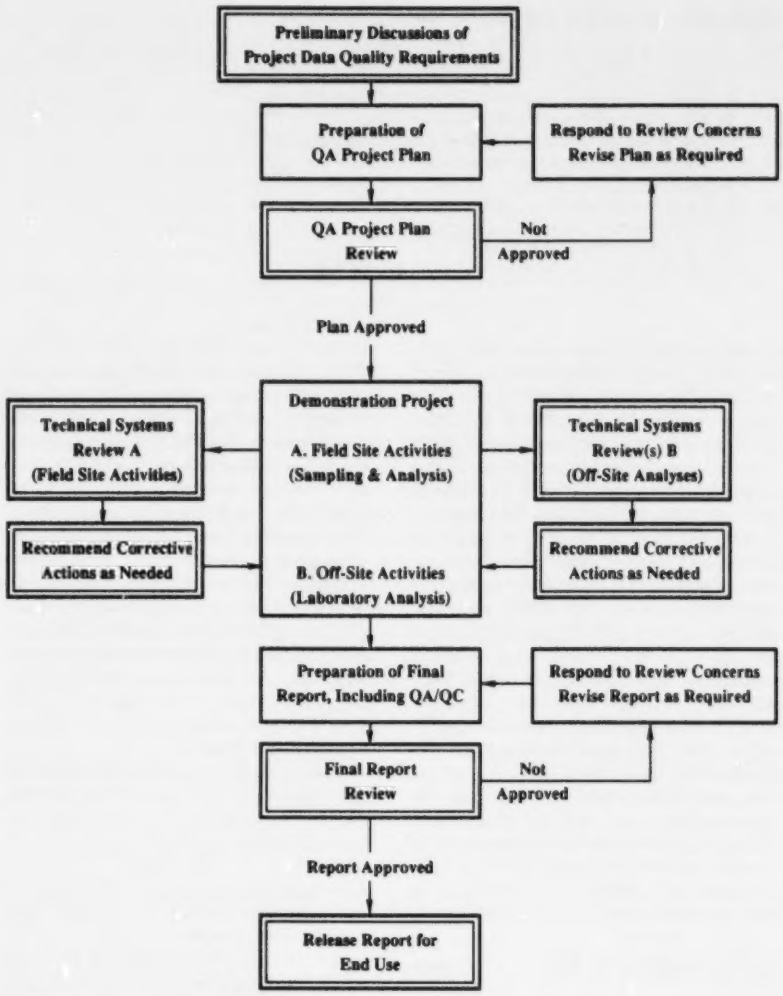
Preliminary Discussions of Project Data Quality Requirements
Preparation of QA Project Plan
Respond to Review Concerns Revise Plan as Required
QA Project Plan Review
Not Approved
Plan Approved
Demonstration Project
A. Field Site Activities (Sampling & Analysis)
B. Off-Site Activities (Laboratory Analysis)
Technical Systems Review A (Field Site Activities)
Technical Systems Review(s) B (Off-Site Analyses)
Recommend Corrective Actions as Needed
Recommend Corrective Actions as Needed
Preparation of Final Report, Including QA/QC
Respond to Review Concerns Revise Report as Required
Final Report Review
Not Approved
Report Approved
Release Report for End Use

Figure 2. The SITE Program Quality Assurance Process.

TABLE II. QA project plan element for site projects.

1. Project description, including project schedule, objectives, and intended use of data.
2. Organization chart and delineation of QA responsibilities.
3. Quality assurance objectives for critical measurements.
4. Sampling and sample custody procedures.
5. Analytical procedures, including sample preparation.
6. Data reduction, validation, and reporting.
7. Internal QC Checks.
8. Plans for systems and performance audits.
9. Calculation of data quality indicators.
10. Corrective action procedures.
11. QA/QC reporting requirements and procedures.

prime contractor, in conjunction with the EPA Project Officer and the S&A contractor, prepares a report that not only presents the results of analysis, but that also reports on (a) the performance and design parameters of the treatment system; (b) the treatment process efficiencies (e.g., the destruction and removal efficiency of toxic and hazardous substances); (c) the generation of process residues and wastes; (d) operational safety, reliability, and variability; (e) the procedures for system set-up, start-up, decontamination, and takedown; and (f) the QA data necessary to ensure compliance with EPA analytical protocols and guidelines. Finally, the EPA uses inputs from the technology developer and the prime contractor to prepare a report on the accumulated cost and schedule data. The integrated demonstration report is used as the basis for evaluating the limitations and range of applicability of the new waste treatment technology.

The QA Program for SITE

In order to ensure that the quality of the results presented in a SITE Demonstration Report is known and is also adequate for the evaluation of a given technology's capabilities and limitations, RREL has established a rigorous quality assurance program for SITE projects. As defined by RREL: "Data quality is known when specific, correctly defined, correctly determined Data Quality Indicators (DQI), such as precision, accuracy (or bias), representativeness, completeness, comparability, and method detection limit (MDL), accompany the data." [4] Furthermore, as stated in EPA Order 5360.1: "The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible." [5]

In addition to these complementary criteria for *known* data quality are the criteria for *adequate* data quality. Adequacy criteria tend to be specific to the innovative technology under evaluation and to the design of the demonstration plan for that technology. For example, American Combustion, Inc., claims that its Pyretron™ burner system "is capable of achieving the RCRA-mandated 99.99 percent destruction and removal efficiency (DRE) of principal organic hazardous constituents (POHC) in wastes incinerated at a higher waste feedrate than for conventional air-only incineration." [3] If this claim is to be evaluated, then not only must the demonstration plan specify the "higher" waste feedrate, but it must also provide that the process effluent (e.g., stack gas) samples are of sufficient size for a calculation of DRE to be significant to at least 99.99 percent under the specifically defined precision, accuracy, and detection limit constraints of the POHC determinative methods.

The overall QA process for the SITE Demonstration Program, illustrated in Figure 2, provides for the establishment of criteria for both the "knowability" and the "adequacy" of project data quality and begins with the preliminary discussions of project data quality requirements conducted between RREL, the technology developer, the prime contractor responsible for the technology evaluation, and the end use of the data (usually the EPA). These discussions result in the development of general, mutually agreed-upon Data Quality Objectives (DQO's) for the demonstration. These general DQO's provide the basis for the development of a formal, detailed QA Project Plan.

Since a QA Project Plan's specifications have their greatest impact on the sampling and analytical activities that generate the critical data for the demonstration project, the EPA's sampling and analytical contractor is usually given the task of preparing it. The form and content of each plan follows the specific guidance provided by QAMS[6] and elaborated by RREL.[7] Table II lists the 11 essential QA Project Plan elements required for SITE projects.[2] Briefly described, each SITE QA Project Plan must include the following information:

- *Project description.* Provides the minimum detail needed for a basic understanding of the treatment technology process. This description must include a quantitative description of project objectives, a clear statement of the intended use of measurement data, and a brief project schedule.
- *Project organization and responsibilities.* Presents a clear delineation of organizational structure and the QA and reporting responsibilities of the key personnel involved in the project. An organization chart is required, and, if subcontractors are employed, they must be identified and their project/QA responsibilities and reporting procedures must be specified.
- *QA objectives.* Defines and lists the specific, and, where possible, quantitative objectives for precision, accuracy, representativeness, completeness, comparability (commonly abbreviated "PARCC"), and method detection limits (MDL) for each critical measurement (i.e., each target analyte and characterization test parameter used to evaluate the technology). QA objectives must be adequate to achieve project and regulatory goals, and at the same time must be achievable by the proposed analytical methods. QA objectives thus provide the focus for all QA planning and measurement activities.
- *Sampling and sample custody.* Specifies the detailed procedures and requirements for collection, preservation, transportation, storage, and documentation of all project samples. The preparation, calibration, cleaning, use, and materials of construction of each item of sampling equipment and/or each type of sample container must also be described or referenced from EPA-approved methods manuals.
- *Analytical procedures.* Provides specific references to standard, EPA-approved sample preparation and analytical methods and procedures used to make critical measurements, or present detailed descriptions of such procedures for nonstandard methods. The calibration requirements for each critical measurement method must also be specified by exact reference or by detailed description. Appropriate validation data must be presented for all nonstandard methods described.
- *Data reduction/validation/reporting.* Presents detailed procedures and requirements for all data processing, review, and report preparation activities. Specific procedures for the identification and treatment of outliers must also be described.
- *Internal QC checks.* Specifies all of the quality control samples required for all critical measure-

ments. Included are the specific compositions and measurement frequencies of all calibration blanks and standards, all field and method blanks, all field and laboratory duplicates, all internal standards, surrogates, and matrix spikes, etc.

- *Systems and performance audits.* Describes the standard, laboratory-internal procedures and criteria for conducting technical systems and performance evaluation audits; provide QA policy statements regarding the participation in any external audits scheduled by, or under the auspices of, RREL QA Management.
- *Assessment of data quality indicators.* Defines the specific procedures and formulas for calculating the precision, accuracy, completeness, and MDL for critical measurements from the appropriate internal QC check data.
- *Corrective action procedures.* Presents the detailed procedures by which out-of-control conditions are identified and corrected.
- *QA/QC reports.* Describes the reporting requirements for the project and includes a QA policy statement specifying the preparation of a separate section in the final project report that presents and discusses all QA/QC data, activities, and results.

Once such a QA Project Plan has been prepared and submitted, it undergoes an intensive, critical review, usually within one week of receipt. Independent reviews are conducted by at least two, and, with increasing frequency, by three, separate reviewers. RREL QA Management conducts these reviews in concert with several QA support specialist groups, including those of PEI Associates, Research Triangle Institute, and the S-CUBED Division of Maxwell Laboratories, Inc. The individual review concerns are then combined, and the composite QA Project Plan review is forwarded to the EPA Project Officer and the SITE Demonstration Project Management with specific recommendations for any plan revisions that may be required.

Revised QA Project Plans are resubmitted, also usually within one week, and the review cycle continues until all deficiencies that would have an adverse impact on the achievement of project objectives have been corrected. The accelerated schedules for review and revision of SITE QA Project Plans have been established to minimize delays in innovative technology demonstrations, in keeping with the spirit of SARA. The average SITE Demonstration QA Project Plan goes through about 2.5 review/revision cycles prior to approval for use. In about a third of all cases, subsequent revisions to already-approved plans are prepared to document changes made as a result of new information obtained immediately prior to or early in the actual demonstration. The end result of the QA Project Plan process is a detailed "blueprint" for conducting a technology demonstration whose results can be assured to be of known quality.

Once the QA "blueprint" has been approved and the demonstration has begun, it becomes necessary to determine whether that "blueprint" is being followed correctly. To make this determination, RREL QA Management and its support service staff conduct a series of Technical Systems Reviews (TSR's). At each major stage of a demonstration project (i.e., during the on-site field sampling and analysis activities and at each off-site laboratory) a team of QA auditors examines every aspect of sampling, analysis, and data handling to ensure that all work is performed according to (a) the specifications of the approved QA Project Plan; (b) the reference methods and procedures cited therein; and (c) good laboratory practices.[8] Significant discrepancies, as well as significant achievements, are noted. Before leaving the site, the QA auditors discuss their findings with the laboratory management. Any critical concerns, especially those that require prompt corrective action, are briefly summarized on a written form, one copy of which is left with the laboratory. Within two weeks, a more detailed draft summary report of the review findings is sent to project management for review and comment, and within 30 days a final TSR Summary Report, complete with corrective action recommendations, project management responses, and an evaluation of the impact to the project of any problem conditions, is prepared and submitted to the RREL QA Manager. The short response and reporting periods for SITE project TSR's are, once again, in keeping with SARA. More importantly, however, prompt corrective action, if needed, can often be implemented on the spot to reduce or eliminate any concerns with data quality.

RREL QA Management occasionally employs performance evaluation audits (requiring the laboratory to analyze check samples prepared by EPA) and audits of data quality (a post-facto examination of analytical records) to supplement the TSRs. Yet, the TSR remains the most valuable of these QA audit types because of its project-specific nature and its ability to provide timely recommendations for corrective action.

TABLE III. SITE QA program status.

Developer/technology	QA project plan reviews	Technical systems reviews	Final report reviews
First SITE Solicitation (SITE-001)			
American Combustion; Pyretron™ Burner	2	5	1
Haztech/Shirco; IR Thermal Destruction	5	3	1
Shirco Infrared Systems; IR Thermal Destruction	3	4	1
Hazcon; Solidification/Stabilization	2	4	1
Westinghouse Electric; Pyroplasma System	a	—	—
Westinghouse Electric; Electric Pyrolyzer	b	—	—
Terra Vac; In-Situ Vacuum Extraction	2	4	1
Ogden; Circulating Bed Combustor	2[e]	—	—
Resources Conservation; Solvent Extraction (BEST)	d	—	—
International Waste Tech; In-Situ Solidification	3	2	2
Detox Industries; Biological Degradation	2[b]	—	—
Second SITE Solicitation (SITE-002)			
Air Products; Fluid Bed/Biological	b	—	—
GeoSafe; In-Situ Vitrification	f	—	—
CF Systems; Solvent Extraction	3	4	—
Chemfix Technologies; Chemical Fixation	1	—	—
MoTec; L/S Contact Digestion	d	—	—
Retech; Plasma Heat	2[e]	—	—
Sanitech; Ion Exhange	f	—	—
Separation and Recovery; Solidification/Stabilization	f	—	—
Soliditech; Solidification	3	2	—
Waste Chem Corporation; Solidification	d	—	—
Zimpro Environmental; Activated Carbon/Biological	f	—	—

[a] Waste for demonstration currently under investigation.
[b] Project removed from active status.
[c] Negotiations with developer, site regulators, and community groups in progress.
[d] Negotiations for demonstration site in progress.
[e] Resolution to QA Project Plan review concerns in progress.
[f] Site selection in progress.

The last step in the quality assurance process for the SITE Demonstration Program is the final report review. These reviews provide detailed evaluation of the technical and QA/QC results in terms of (a) the credibility of the data; (b) applicability of data to project objectives; (c) the comparability of the data to other SITE and related projects; (d) the validity of any conclusions; and (e) the quality of data. These findings provide guidance for recommending revisions to the report and for assessing the overall applicability of the innovative technology.

Results and Conclusions

The utility of the SITE quality assurance program can best be judged by examining its effect on current SITE projects. Consider first the impact of the Quality Assurance Project Plans which are developed during the early planning stages of the project. As can be seen in Table III, QA Project Plans for a total of eleven projects have been reviewed (consisting of 27 drafts). While some QA Project Plans are approved in the first draft, more typically, two drafts are required, due to significant deficiencies in the first. Problems commonly found in the first draft include (a) incorrect sampling and analytical methods; (b) poorly defined objectives; (c) incomplete or inappropriate procedures for measuring precision, accuracy or detection limit; or (d) sampling strategy which is mismatched to project objectives. Such substantive deficiencies, which otherwise would harm project performance, are then corrected in a second draft prior to sample collection and analysis.

Similarly, Technical Systems Reviews (TSRs) conducted during the early stages of the sampling and analytical phase have resulted in significant impacts on the courses of various projects. TSRs of SITE projects have identified and corrected potentially critical problems in contractor analytical laboratories. For example, a recent TSR of the analytical laboratory performing PCB determinations in support of a SITE project revealed that the analytical laboratory had not performed any of the QC determinations which were required by the QA Project Plan. Without these QC determinations, the data for these critical analyses would have been unknown and any assessment of the SITE technology would necessarily have been tentative. In this instance, corrective action recommended during the TSR was implemented early enough to allow generation and documentation of the required QC data for all critical PCB measurements. In extreme cases, laboratories have been temporarily suspended from participation in the SITE program as a result of an unfavorable TSR. Such action has resulted when laboratories were completely unprepared to begin sample analysis or when QA requirements were entirely ignored. In these instances, the suspended laboratories subsequently implemented corrective action that was recommended during the TSR, and follow-up reviews found that all major problems had been rectified and that the laboratory could be expected to generate data of good quality with proper documentation. While it is fortunate that such drastic action is seldom required, TSRs of even well-run laboratories typically result in the identification and correction of either technical or management concerns.

Audits of Data Quality (ADQ), though employed less frequently than TSR's, nevertheless often reveal significant problems. As an example, an ADQ of a recent project demonstrated that analytical recovery data had been calculated incorrectly by the laboratory. In this case, the recalculated data proved more favorable to the developer than the original data. Under less favorable conditions, other ADQ's have revealed substantial problems with data quality, leading to the recognition that certain key data were estimates only and could not be interpreted with the confidence originally intended.

The last stage of the QA process is the review of the final reports. Generally, SITE contractors at this stage are well informed and report quality assurance data as an integral part of the report. However, the final report review process often reveals the need for additional interpretation of QC data and its impact on the validity of any conclusions.

It must be emphasized that the external review process afforded by the SITE Quality Assurance Program is no substitute for the commitment of knowledgeable project staff, who are directly responsible for the quality of the work performed. However, unlike a project involving a single principal investigator at a given location, SITE projects tend to require the coordinated efforts of regulators, managers, engineers, chemists, statisticians, and economists, and under these circumstances it is not surprising that many of the problems revealed by the review process arise not from lack of dedication on the part of project members, but rather from communication problems among the diverse parties involved. Chemical analysts may be unaware of regulatory or engineering objectives, engineers may be misinformed regarding analtyical limitations and possibilities, the sampling team may lack instructions regarding sampling requirements, and managers may have unrealistic expectations regarding the readiness of the project team. It is precisely because of the complicated nature of SITE projects that such potential problems arise, and it is for this reason that the quality assurance review process has come to play a significant role in the SITE program.

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